

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,749	09/21/2001	Thomas E. Borillo	593/005	5029

1473 7590 06/05/2003
FISH & NEAVE
1251 AVENUE OF THE AMERICAS
50TH FLOOR
NEW YORK, NY 10020-1105

EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
----------	--------------

3731

DATE MAILED: 06/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/960,749

Applicant(s)

BORILLO ET AL.

Examiner

Jessica R Baxter

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 Jan 2002, 7 March 2003 21 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,5 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group IV in Paper No. 4 is acknowledged. The traversal is on the ground(s) that the groups are linked by securement means structure in Groups II and IV. This is not found persuasive because Group II also claims an additional step of puncturing and dilating the septum. This step is not required by Group IV and would require a further search to find the structure and step of puncturing and dilating the septum. Group II does not require the use of a positioning guide as claimed in Group IV. If Group II had been selected, a positioning guide would require an additional search. Thus, Group II and Group IV are separate inventions.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 14, 15, 20 and 242. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 28, 33 and 35 are objected to because of the following informalities:

- a. In claim 28 line 23, change "appendage" to --appendage.--
- b. In claim 33 line 2, change "providing lumen" to --providing a lumen--
- c. In claim 35 line 5, change "tube" to --tube.--

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 28-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 28 recites the limitation "said sheath assembly" in 13. There is insufficient antecedent basis for this limitation in the claim.
7. Claim 28 recites the limitation "the ostium" in line 18. There is insufficient antecedent basis for this limitation in the claim.
8. Claim 29 recites the limitation "providing a positioning guide" in line 3. It is unclear whether this is the same structure that is already recited in claim 28 or an additional structure.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 28, 30 and 31-33 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S.

Patent No. 6,152,144 to Lesh et al.

Art Unit: 3731

Regarding claim 28, Lesh discloses a method comprising the steps of providing a catheterization apparatus comprising: a tube assembly (apparatus 150), said assembly comprising at least an outer tube (shaft 151); a shaft (shaft 174); and a positioning guide (members 155); percutaneously advancing said tube assembly through a blood vessel to establish a passageway to said atrium (Column 3 line 30 – Column 4 line 3); introducing said positioning guide to a location about the ostium of said appendage (FIGS 21 and 22); deploying said positioning guide to engage atrial wall portions (FIG. 22); and using said shaft to transport said device through said passageway to a position within said appendage (FIG. 21).

Regarding claims 30 and 31, Lesh discloses that said reversibly expandable structure comprises providing at least a preformed wire configuration (members 155 and Column 13 lines 41-47).

In another embodiment:

Regarding claim 28, Lesh discloses a method comprising the steps of providing a catheterization apparatus comprising: a tube assembly, said assembly comprising at least an outer tube (catheter 111); a shaft (shaft 121); and a positioning guide (member 114); percutaneously advancing said tube assembly through a blood vessel to establish a passageway to said atrium (Column 3 line 30 – Column 4 line 3); introducing said positioning guide to a location about the ostium of said appendage (FIG. 16); deploying said positioning guide to engage atrial wall portions (FIG. 16 and Column 11 lines 27-38); and using said shaft to transport said device through said passageway to a position within said appendage (FIG. 16).

Regarding claims 30 and 32, Lesh discloses that said positioning guide further comprises providing a positioning guide having a reversibly expandable structure comprising an inflatable balloon (inflatable member 114).

Art Unit: 3731

Regarding claim 33, Lesh discloses that said tube assembly further comprises providing a lumen (Column 11 lines 27-38).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 28-31 and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesh et al. '144 in view of U.S. Patent No. 5,797,960 to Stevens et al.

Regarding claims 28, 29 and 35-38, Lesh discloses a method comprising the steps of providing a catheterization apparatus comprising: a tube assembly (apparatus 150); a shaft (member 161); and a positioning tube (shaft 174) with a positioning guide member on an end (members 155); percutaneously advancing said tube assembly through a blood vessel to establish a passageway to said atrium (Column 3 line 30 – Column 4 line 3); introducing said positioning guide to a location about the ostium of said appendage (FIGS 21 and 22); deploying said positioning guide to engage atrial wall portions (FIG. 22); and using said shaft to transport said device through said passageway to a position within said appendage (FIG. 21). Lesh does not disclose an outer tube assembly with securement means to engage surface portions of a septum traversed by the outer tube. Stevens teaches that an outer tube with securement means is provided to allow the introduction of instruments for visualization and intervention through the outer tube and to provide a securement means that prevents leakage of blood (Column 13 lines 24-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tube assembly of

Art Unit: 3731

Lesh with an outer tube in order to facilitate the insertion of instruments into the heart and to seal the opening in the heart from blood leakage.

Regarding claims 30 and 31, Lesh discloses that said reversibly expandable structure comprises providing at least a preformed wire configuration (members 155 and Column 13 lines 41-47).

Regarding claim 34, Lesh discloses that the step of providing said tube assembly further comprises providing a delivery tube (shaft 151) for advancing said positioning guide through said tube assembly to a location proximate to said appendage (FIG. 21), and wherein said delivery tube retractably extends through said outer tube.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to further show the state of the art with respect to similar devices:

U.S. Patent No. 4,753,637 to Horneffer

U.S. Patent No. 6,231,544 to Tsugita et al.

U.S. Patent No. 4,836,204 to Landymore et al.

U.S. Patent No. 6,235,044 to Root et al.

U.S. Patent No. 5,312,341 to Turi

U.S. Patent No. 6,328,757 to Matheny

U.S. Patent No. 5,545,214 to Stevens

U.S. Patent No. 6,419,669 to Frazier et al.

U.S. Patent No. 5,655,548 to Nelson et al.

U.S. Patent No. 6,551,303 to Van Tassel et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731


jrb

May 28, 2003


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700